

**REMARKS**

Claims 1-3, 6 and 7 stand rejected. Applicant respectfully requests reconsideration of the rejection in view of the following arguments.

35 U.S.C. § 112

Claims 1-3, 6 and 7 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the enablement requirement. The Office Action alleges that the claims contain subject matter which was not described in such a way to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant traverses this rejection for the reasons indicated below.

One skilled in the art of culturing tumor cells would be able to make and use the claimed invention based upon the Applicant's disclosure. Specifically, one skilled in the art of culturing tumor cells has knowledge regarding optimal culture mediums for particular tumor cell types. Furthermore, those skilled in the art of culturing tumor cells would also be readily aware of culture medium preferences of particular tumor cell types such that they would be able to choose specific amounts of each ingredient in a culture medium based on the claimed range of values in the present application. The Examiner asserts on page 3, lines 14-15 that one skilled in the art would not have unlimited amounts of tissue to commit to optimization studies. However, the culture medium does not need to be optimized for each individual biopsy. Instead, a culture medium that has been optimized for a particular tumor cell type can then be used for every biopsy of that tumor type. Thus optimization is not necessary for each individual biopsy. Further, even if the biopsy is from an unknown tumor type, preliminary examination and clinical knowledge will provide a person of skill in the art with a fair prediction of the likely tumor types, and multiple media optimized for these tumor types can be utilized. Therefore, the medium need only be optimized to support growth of the tumor cell type, which is well within the grasp of those skilled in the art of culturing tumor cells.

Furthermore, just because none of the "classic media" contain both  $\text{Ca}(\text{NO}_3)_2$  and  $\text{CaCl}_2$  does not mean that those skilled in the art would be incapable of readily determining the appropriate amounts of each component. As previously presented, these compounds dissociate into the ionic components, which have known effects regarding tumor cell culture growth. Just because the overall compounds have not been used together in the "classic media" does not mean that one skilled in the art would be unable to easily determine the appropriate amounts of each compound to acquire the desired amount of the ionic components.

Regarding the Examiner's concern to suppress overgrowth of contaminating connective tissues and vascular cells, this information is well within the knowledge of those skilled in the art. Suppression of connective tissue and vascular cell overgrowth is not related to the specific tumor cell type, but instead common conditions for suppression of connective tissue and vascular cell overgrowth can be applied to the culture medium regardless of the type of tumor. The culture medium does not have to be optimized for suppression of connective tissue and vascular cell overgrowth for each tumor cell type. Accordingly, this knowledge of those skilled in the art can be used to help choose the specific amounts of each ingredient based upon the ranges disclosed by Applicant and recited in the claims. Furthermore, the separation of tissue samples into disk segments and subsequently into fragments, as recited in claim 1, also contributes to the suppression of connective tissue and vascular cell overgrowth.

Regarding the Examiner's comments on page 3 in the first full paragraph, the Examiner has misunderstood the thrust of the Applicants' argument. Applicant is not asserting that these are alternatives such that the range for the components indicated is zero. Instead Applicant was highlighting that the compounds exist in the ionic components. However, each of the recited compounds in claim 1, with the exception of  $\alpha$ -tocopherol phosphate, exists in the composition and is not being asserted as an alternative such that the range for any of the components besides  $\alpha$ -tocopherol phosphate is zero.

CONCLUSION

Applicant respectfully requests reconsideration of the rejection of claims 1-3, 6 and 7 and allowance of the case. Should additional fees be required in connection with this matter, please charge our Deposit Account No. 23-0785 the necessary amount.

Respectfully submitted,

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By

  
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